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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,168	01/22/2002	Bernhard Nieswandt	08698.0002	7939

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EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,168	NIESWANDT, BERNHARD	
	Examin r	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-9 and 11-16* is/are pending in the application.

4a) Of the above claim(s) *7,8,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/21/03 (Paper No. 10), is acknowledged.

2. Claims 1-3, 5-9, 11-16 are pending.

3. Claims 7-8 and 15-16 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims1-3, 5-6, 9 and 11-14 are under consideration in the instant application.

5. In view of the amendment filed on 4/21/03 (Paper No. 10), only the following rejections remained.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 5 and 13-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

> Claims 3, 5 and 13-14 are indefinite in the recitation of "JAQ1" because its characteristics are not known. The use of "JAQ1" monoclonal antibody as the sole means of identifying the claimed antibody and hybridoma renders the claim indefinite because "JAQ1" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct hybridomas or cell lines. It is suggested that the DSM ACC 2487 be cited in the claims.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that an applicant is entitled to be his own lexicographer as long as the term used is defined in the present specification as is not repugnant to those of skill in the art. Applicant contends that the specification indicates that JAQ1 is a monoclonal antibody that is secreted by the hybridoma cell line DSM ACC 2487.

However, "JAQ1" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct hybridomas or cell lines.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3, 5, 9 and 13-14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant requests that the Office hold this enablement rejection in abeyance until the Deposit Declaration is submitted.

10. Claims 1-3, 5 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the JAQ1 antibody which specifically binds GPVI for diagnostic assays, does not reasonably provide enablement for **any medicament** for protection against thrombotic diseases involving platelet collagen receptor glycoprotein VI (GPVI), comprising at least one **active principal** that induces an irreversible inactivation or degradation of a GPVI collagen receptor on thrombocytes, wherein the medicament is in the form of a physiologically acceptable injection in claim 1; wherein the at least one active principal is **any antibody** in claim 2, wherein the at least one active principal is monoclonal antibody JAQ1 in claim 3, wherein the at least one active principal is humanized monoclonal antibody JAQ1 in claim 5; a method of producing **any medicament** against thrombotic diseases comprising providing at least **one active principal** that induces an irreversible inactivation or degradation of a GPVI collagen receptor on thrombocytes, combining the at least one active principal with a physiologically acceptable carrier to form a physiologically acceptable injection medicament in claim 11, wherein the at least one active principal is **any monoclonal antibody** in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that it is well known to those of skill in the art that once an antibody having a specific binding characteristic is obtained, it can be used to identify multiple other substances that have the same binding characteristic. Applicant further argues that combinatorial chemistry and high throughput screening are standard techniques used in the art, and one of skill in the art would know to apply these techniques to develop active principals according to the present claims. Making such active principals is thus well within the skill of those of skill in the art, and does not represent undue or excessive experimentation. Applicant further agues that the amendment to the claims to recite the medicament protect against thrombotic diseases involving

platelet collagen receptor glycoprotein VI (GPVI) overcome the rejection regarding the claimed medicament would function to protect " against thrombotic diseases".

Contrary to Applicants' assertions, beside JAQ1 antibodies, the specification fails to provide any other "active principal". Further, in order to satisfy the U.S.C 112, 1st paragraph, the specification has to teach how to make and/or use the invention, not how to identify multiple other substances of the invention. Until the time when other substances are found, then one skill in the art can make them.

Regarding the a medicament, in view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the medicament as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed medicaments are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed medicament with a reasonable expectation of success.

Consequently, without additional guidance in the specification, and the dearth of information in the art, for one of skill in the art to practice the invention with the different diseases as claimed, would require experimentation that is excessive and undue. The amount of guidance or direction needed to enable an invention is inversely related to the mount of knowledge in the state of the art as well as the predictability in the art (*In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18,24 (CCPA 1970)).

11. Claims 1-3, 5 and 11-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that there is not necessary that an applicant be in physical possession of all species encompassed by a generic claim. Applicant further argues that an adequate written description can be achieved by the disclosure of a single working example, the antibody JAQ1.

However, the Examiner notes that the claimed invention which is drawn to a genus may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. To satisfy the disclosure of a "representative number of species" will depend on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. "Relevant,

identifying characteristics" include structure or other physical and /or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus. (see Revised Guidelines for the Examination of Patent Applications Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001).

In the instant case, however, there is no described or art-recognized correlation or relationship between the structure of the invention, the JAQ1 and it's inactivation or degradation function, the feature deemed essential to the instant invention. Therefore, one of skill in the art would not envisage, based on the instant disclosure, the claimed genus of active principal, wherein the active principal is an antibody.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 9 and 11-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nieswandt *et al* (IDS ref No. 7) (J Biol Chem. 275(31):23998-4002, August 2000) essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that if an independent claim is not anticipated by a reference, then its dependent claims cannot be anticipated because, by definition, dependent claims include all of the elements or steps of the claim(s) from which they depend. Applicant concludes that independent claims 1, 9, 11 are not anticipated by Nieswandt et al., then claims 2, 3, 5, 6, and 12-14 are not anticipated.

Contrary to applicant assertions, Nieswandt *et al* anticipate the independent and dependent claims. Further, Nieswandt et al teach the JAQ1 antibody in a composition e.g 20 μg/ml and 10 μg/ml (see figures 1-4, in particular). Further, Nieswandt et al teach the JAQ1 antibody in HAT medium (see page 23999) which is considered to be a physiologically acceptable injection.

Therefore, the reference teachings anticipate the claimed invention.

14. Claims 1-2 and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Clemetson *et al* (IDS ref No. 6) (J Biol Chem. 274(41):29019-24, 1999) essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that independent claims 1 and 11 now recite a physiological acceptable injection, wherein Clemetson et al do not anticipate both claims.

Contrary to applicant assertions, Clemetson *et al* teach that antibody fragment in 140 mM NaCl, 4 mM KCl, 20 mM Hepes, pH 7.4 (see page 29020 under (preparation of anti-GPVI Fab and $F(ab')_2$). Clemetson et al further teach that the GPVI was eluted in 10 mM Tris/HCL, pH7.4 containing 0.1% octyl-N-methylglucamide (see page 29020 under GPVI isolation from platelets), wherein the purified GPVI was used to prepare in rabbits polyclonal antibodies that recognized a single band in blots from whole platelet lysate at 65 kDa (see page 29021, 1st column, 1st paragraph in particular). Both 140 mM NaCl, 4 mM KCl, 20 mM Hepes buffer and 10 mM Tris/HCL buffer are considered to be a physiologically acceptable injection.

The reference teachings anticipate the claimed invention.

15. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Buchanan *et al* (Thrombosis Research 29:125-1983) essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that Buchanan et al do not teach the medicament in the form of a physiologically acceptable injection, thus does not anticipate independent claim 1.

Contrary to applicant assertion, Buchanan et al teach the aspirin in sodium carbonate buffer (see page 126 last paragraph in particular). Sodium carbonate buffer is considered to be a physiologically acceptable injection.

Therefore, the reference teachings anticipate the claimed invention.

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nieswandt *et al*, in view of Owens *et al* (1994) essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that Nieswandt.et al do not suggest such a medicament neither do Owens et al provide the missing element. Thus the combination fails to render claim 1 and its dependent claim 5 obvious.

Contrary to applicant assertion, Nieswandt et al do teach the monoclonal antibody HAT media. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to produce the monoclonal antibody taught by Nieswandt *et al* as humanized antibody as taught by the Owens *et al.*

18. Claim 6 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nieswandt *et al* or Clemetson *et al* in view of U.S. Patent No. 6,406,888 essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that Nieswandt et al do not suggest such a diagnostic agent and likewise, Clemetson et al do not disclose or suggest such a diagnostic agent. The `888 patent fails to provide this missing element. Thus the combinations of Nieswandt et al and the `888 patent, and of Clemetson et al and the `888 patent fail to teach each and every limitation of claim 6. thus the combinations fail to render claim 6 obvious.

In response to applicant's arguments against the references individually, one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

19. Claims 11 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Clemetson *et al* (IDS ref No. 6) in view of in view of Harlow (1989) essentially for the same reasons set forth in the previous Office Action, paper No. 8, mailed 10/22/02.

Applicant's arguments, filed 4/21/03 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant argues that Clemetson et al do not disclose a method for producing a medicament comprising providing at least one active principal and combining the principal with a physiological carrier, Further Clemetson et al do not suggest such a method. Harlow fails to disclose or suggest such a method. Applicant argues that Harlow fails to provide and element missing from Clemetson et al that is needed to achieve present claim 11. As such, the combination of Clemetson et al and Harlow fails to teach each and every limitation of claim 11 and its dependent claim 12.

However, once a prima facie case of obviousness has been made the burden of going further is shifted to applicant. In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981). This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

20. No claim allowed

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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May 1, 2003

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